



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/913,898	10/03/2001	Zhiyuan Gong	1781-0163P	5940

7590

12/21/2005

DAVID L. PARKER
FULBRIGHT & JAWORSKI L.L.P.
600 CONGRESS AVE.
SUITE 2400
AUSTIN, TX 78701

EXAMINER

WOITACH, JOSEPH T

ART UNIT

PAPER NUMBER

1632

DATE MAILED: 12/21/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/913,898	Applicant(s) GONG ET AL.	
	Examiner Joseph T. Woitach	Art Unit 1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 September 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 7-11, 13, 19-21, 23, 24 and 30 is/are pending in the application.
4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 7-11, 13, 19-21, 23, 24 and 30 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 8/17/2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This application is a 371 national stage filing of PCT/SG99/00079, filed July 16, 1999 which claims benefit to foreign application 9900811-2, filed February 18, 1999 in Singapore.

Applicants' amendment filed September 21, 2005, has been received and entered. Claims 1-7, 12, 14-18, 22, 25-29 have been canceled. Claim 30 has been added. Claims 7-11, 13, 19-21, 23, 24 and 30 are pending.

Election/Restriction

Applicant's election without traverse of group VIII in the reply filed on August 27, 2003 was acknowledged. Newly added claim 30 is encompassed by the elected invention. Applicants have canceled the previously withdrawn claims.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Claim Objections

Claim 7 has been cancelled.

Claim 10 objected to because it was generic and broadly encompasses non-elected inventions is withdrawn.

Art Unit: 1632

The amendment to claim 10 has obviated the basis of the objection.

Newly amended claim 8 is objected to because it was generic to more than the elected invention of the fast muscle isoform of myosin light chain 2 gene promoter.

Newly amended claim 23 is objected to because it is directed to a promoter other than the elected invention of the myosin light chain 2 gene promoter.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 7-11, 13, 19-21, 23, 24 and newly added claim 30 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention.

Applicants do not address the basis of this rejection, and therefore, they are maintained for the reasons on record. To the extent that applicants' arguments regarding the new matter rejection of claim 16 apply to the instant rejection, it is noted that the claims have been amended to recite a creatine kinase promoter (drawn to a non-elected invention) and the myosin light chain 2 promoter, however this fails to address the fact that the only promoter disclosed with any functional properties is those provided as the full length SEQ ID NOs in the present specification. There is no guidance in the present specification for any modification of these

Art Unit: 1632

sequence set forth as SEQ ID NOs, nor means of obtaining or details of other sequences that meet the structural and functional limitations of such promoters. Moreover, it is noted that the present specification even teaches that “expression pattern of a transgene in many cases is variable and unpredictable” describing the need for identifying and characterizing non-heterologous promoters in fish (page 2, lines 25-30).

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 19 stands rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Applicants’ comments regarding ornamental fish, and evidence provided for support of ornamental fish are noted, however listing of fish sold as ornamental fish, or tariff code provisions fails to address the fact that these are intended uses of the fish. Each fail to uniquely define a fish. For example, Applicants indicate that members of catfish, tilapia and eel family are marketed as ornamental fish, however it is note that these are also marketed and imported as food products. Applicants comments regarding ornamental plants are noted, however the reasoning for the classification of plants is beyond the scope of this office action, and is not salient to transgenic animals which has no such subclass.

Newly amended claim 9 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Specifically, the claim is unclear and confusing, because there is insufficient antecedent basis for why or how the fish emits green fluorescence, since no

Art Unit: 1632

specific transgene is recited nor required in claim 8. While certain fish are known to be fluorescent, it is unclear if this in reference to such fish, or to the consequence of the transgene expression. Amending the claim to be dependent on claim 10, or more clearly setting forth the transgene encodes a green fluorescent protein would address the basis of the rejection.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims previously rejected under 35 U.S.C. 102(b) as being anticipated by Moss *et al.*

(IDS reference) is withdrawn.

Examiner agrees that Moss *et al.* teach a zebrafish which comprises a myosin light chain enhancer operatively linked to a sequence encoding GFP for the muscle specific expression, however that the chimeric fish produced with the methods disclosed would not produce transgenic progeny as required by the instant claims.

Conclusion

No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a).

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

Art Unit: 1632

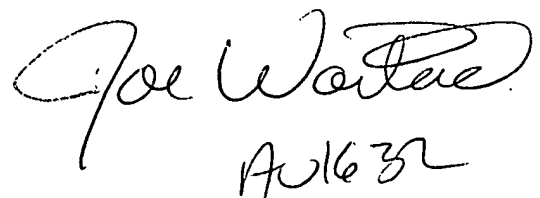
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joseph Woitach whose telephone number is (571) 272-0739.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla, can be reached at (571) 272-0735.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group analyst Dianiece Jacobs whose telephone number is (571) 272-0532.

Joseph T. Woitach



Joe Woitach
AUL632